



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/734,589

12/15/2003

Serengulam V. Govindan

328884

2607

63322 7590 02/12/2009

IMMUNOMEDICS, INC.  
300 AMERICAN ROAD  
MORRIS PLAINS, NJ 07950

EXAMINER

FETTEROLF, BRANDON J

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

02/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Art Unit: 1642

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/17/2008 has been entered.

Claims 1, 5-8, 14-15, 17-30, 32-34, 36-45, 48-73 are pending.

Claims 5-8 and 51-62 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 14-15, 17-30, 32-34, 36-45, 48-50 and 63-73 are currently under consideration.

Note: The species election has been withdrawn.

### **Rejections Withdrawn:**

All previous rejections have been withdrawn in view of Applicants amendments to remove polyethylene glycol. The rejection of Claims 1, 15, 17, 18-30, 32-34, 36-45, 48-50 and 63-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants amendments.

### **New Rejection:**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

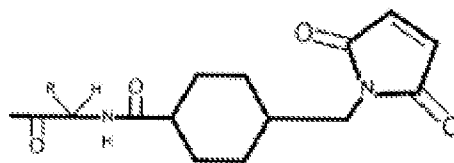
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does

Art Unit: 1642

not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 32 recites the broad recitation of a linker comprising a (i) a thiol reactive functional group that binds to a thiol group on the antibody and (ii) a water-solubilizing moiety selected from the group consisting of ethylenediaminetetraacetic acid (EDTA), diethylenetriaminepentaacetic acid (DTPA), triethylenetetraminehexaacetic acid (TTHA), benzyl-DTPA, 1,4,7,10-tetraazacyclododecane-N,N',N'',N'''-tetraacetic acid (DOTA), benzyl-DOTA, 1,4,7-triazacyclononane- N,N',N''-triacetic acid (NOTA), benzyl-NOTA, 1,4,8,11-tetraazacyclotetradecane- 1,4,8,11-tetraacetic acid (TETA) and N,N'- dialkyl substituted piperazine,



and the claim also recites that the linker is of the formula , wherein wherein R is an amino acid side chain, said amino acid selected from the group consisting of glycine, alanine, valine, leucine, isoleucine, proline, serine, threonine, cysteine, methionine, asparagine, glutamine, phenylalanine, tyrosine, tryptophan, lysine, arginine, histidine, aspartate and glutamate. However, the linker as described in the formula does not comprise the water solubilizing moiety as described by the broad recitation of a linker.

### Conclusion

While the state of the art at the time the invention was made recognizes the use of the claimed water-soluble moieties as chelators for radiometals, the state of the art at the time the invention was made appears to be silent on the use of these agents for linking a chemotherapeutic

Art Unit: 1642

moiety to an antibody. As such, Claims 1, 14-15, 17-30, 33-34, 36-45, 48-50 and 63-73 appear to be in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf  
Primary Examiner  
Art Unit 1642

/Brandon J Fetterolf/  
Primary Examiner, Art Unit 1642